

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

VISION PHARMA, LLC,

Plaintiff,

13 Civ. 2405 (RA) (DCF)

-against-

SUNRISE PHARMACEUTICALS, INC.,

Defendant.

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT SUNRISE
PHARMACEUTICALS, INC.'S MOTION TO DISMISS THE COMPLAINT

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Preliminary Statement

This memorandum of law is submitted by defendant Sunrise Pharmaceutical, Inc. ("Sunrise") in support of its motion for an Order pursuant to Fed. R. Civ. P. 12(b)(1), 12(b)(2), 12(b)(6) and 12(b)(7) dismissing the complaint of plaintiff Vision Pharma, LLC, a limited liability company organized under the laws of Florida ("Vision Florida").

Sunrise is a pharmaceutical company located in New Jersey. In 2006 and 2008 non-party Vision Pharma LLC, a limited liability company organized under the laws of New Jersey ("Vision New Jersey"), engaged Sunrise to manufacture Colchicine .6mg Tablets, Hyoscyamine Sulfate Tablets 0.125mg, Hyoscyamine Sulfate Orally Disintegrating Tablets 0.125mg and Hyoscyamine Sulfate Sublingual Tablets 0.125mg (individually and collectively, the "Drug Products").

Based solely on unenforceable advisory warning letters from a district office of the U.S. Food and Drug Administration (the "FDA") – issued months after the last Drug Products were delivered to Vision New Jersey -- Vision Florida asserts seven claims against Sunrise for breach of contract, breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, breach of covenant of good faith and fair dealing, unjust enrichment, negligence and deceptive trade practice.

As set forth below and in the accompanying declaration of Utpal Patel, Chief Executive Officer of Sunrise, dated June 20, 2013 (the "Patel Decl"), there is no basis for this Court to exercise personal jurisdiction over Sunrise. Sunrise has no jurisdictional contacts with New York. Among other things, Sunrise is not located in New York, has no property, employees or customers in New York and all of the Drug Products were manufactured in New Jersey for a New Jersey based customer and

shipped to Tennessee. It bears emphasis that neither Vision Florida nor Vision New Jersey is located in New York or has any other apparent jurisdictional contacts with New York. Accordingly, this action must be dismissed for lack of personal jurisdiction.

Vision Florida was created on August 28, 2009 – long after Vision New Jersey engaged Sunrise in 2006 and 2008 -- and is not a party to any of the contracts, transactions or events identified in the complaint and which form the bases of Vision Florida's claims. Indeed, the entity with which Sunrise contracted and dealt is non-party Vision New Jersey, and Vision Florida fails to allege any relationship between it and Vision New Jersey. Accordingly, this action must be dismissed because (a) Vision Florida lacks standing to prosecute the claims asserted in the complaint; and (b) Vision New Jersey is a necessary and indispensable party which should – but cannot -- be joined as a party.

Moreover, Vision Florida fails to allege sufficient facts from which the Court may infer that its claims for relief are plausible and that Sunrise is liable. Indeed, Vision Florida does not allege that the specific Drug Products delivered to Vision New Jersey were adulterated upon tender of delivery or at any time thereafter. Vision Florida does not even allege that the Drug Products in general are adulterated. Rather, Vision Florida alleges only that the FDA issued warning letters which labeled unidentified batches of the Drug Products as adulterated. As a matter of law, a warning letter from the FDA is merely advisory, does not constitute the final binding position of the FDA and does not bind the FDA to take enforcement action. It bears emphasis that the warning letters relied upon by Vision Florida were issued many months after the last Drug Products were delivered to Vision New Jersey.

Vision Florida also fails to identify the dates of the transactions and the specific batches of the Drug Products which form the bases of its claims. Nor does Vision Florida allege a causal nexus between the advisory warning letters and its alleged damages. Indeed, Vision Florida does not allege that the FDA ordered a recall of the Drug Products or that Vision Florida was unable to sell the Drug Products. Accordingly, Vision Florida fails to state a claim upon which relief may be granted.

Facts

Sunrise is a pharmaceutical company organized as a corporation under the laws of New Jersey and located in New Jersey. Complaint, ¶ 2; Patel Decl, ¶ 3. Plaintiff Vision Florida is a pharmaceutical company organized as a limited liability company under the laws of Florida and located in Florida. Complaint, ¶ 1. Vision Florida was formed on August 28, 2009.¹ Non-party Vision New Jersey is a pharmaceutical company organized as a limited liability company under the laws of New Jersey and located in New Jersey. Vision New Jersey was formed on April 21, 2003 and was cancelled on October 2, 2009.²

Vision Florida does not allege that it is related, by merger, acquisition, assignment or otherwise, to Vision New Jersey.

In 2006 and 2008 Vision New Jersey engaged Sunrise to manufacture the Drug Products. Complaint, ¶¶ 7 and 8. Although Vision Florida's claims against Sunrise are based primarily on written agreements between Vision New Jersey and Sunrise

¹ A copy of the Detail by Entity Name and Articles of Organization for Vision Florida filed with the Florida Department of State, Division of Corporations is annexed to the Patel Decl as Exhibit A.

² A certified copy of Vision New Jersey's Certificate of Formation is annexed to the Patel Decl as Exhibit C, and a certified copy of Vision New Jersey's Certificate of Cancellation is annexed to the Patel Decl as Exhibit D.

regarding the Drug Products, Vision Florida remarkably chose not to annex those agreements to the complaint.³

It bears emphasis that the Manufacturing Agreements do not contain (a) representations or warranties regarding the quality of the Drug Products or any other matter; and (b) any requirement to provide notice or responses to Vision New Jersey (or Vision Florida) regarding warning letters, 483 observations or any other matter. Moreover, the Manufacturing Agreements do not require Sunrise to provide the Drug Products to Vision New Jersey (or Vision Florida) for a stated period of time or in a stated quantity. Nor do the Manufacturing Agreements identify where Vision New Jersey or Vision Florida intend to sell the Drug Products.

Pursuant to Vision New Jersey's written instructions in its purchase orders, all of the Drug Products manufactured by Sunrise were shipped from Sunrise's New Jersey facilities to a warehouse in Memphis, Tennessee.⁴ The last two accepted and fulfilled Purchase Orders for the Drug Products were issued by Vision New Jersey on August 3, 2009 for Hyoscyamine Sulfate for a total purchase price of \$68,756.60 and on September 11, 2009 for Colchicine for a total purchase price of \$36,000. See Purchase Orders. The Hyoscyamine Sulfate was shipped to Vision New Jersey's Memphis,

³ A copy of the agreement between Vision New Jersey and Sunrise signed on January 1, 2006 and April 13, 2006 for the manufacture of Colchicine .6 mg Tablets (the "2006 Colchicine Agreement") is annexed to the Patel Decl as Exhibit E. A copy of the agreement between Vision New Jersey and Sunrise signed on January 1, 2006 and April 13, 2006 for the manufacture of Hyoscyamine Sulfate Orally Disintegrating Tablets .125 mg (the "2006 Hyoscyamine Sulfate Agreement") is annexed to the Patel Decl as Exhibit F. A copy of the agreement between Vision New Jersey and Sunrise signed on April 25, 2008 for the manufacture of Hyoscyamine Sulfate Tablets .125 mg (the "2008 Hyoscyamine Sulfate Tablet Agreement") is annexed to the Patel Decl as Exhibit G. The 2006 Colchicine Agreement, 2006 Hyoscyamine Sulfate Agreement and 2008 Hyoscyamine Sulfate Tablet Agreement (including Sublingual Tablets) are referred to individually and collectively as the "Manufacturing Agreements."

⁴ Copies of the accepted and fulfilled purchase orders issued by Vision New Jersey (the "Purchase Orders") in 2008 and 2009 and related packing slips (the "Packing Slips") are annexed to the Patel Decl as Exhibits H and I. Sunrise received one other purchase order dated December 14, 2009 from Vision Pharma. That purchase order was not accepted and no Drug Products were sold or shipped in response to that purchase order. Patel Decl, ¶¶ 10, fn 3.

Tennessee warehouse on August 19, 2009 and the Colchicine was shipped to Vision New Jersey's Memphis, Tennessee warehouse on October 9, 2009. See Purchase Orders and Packing Slips. No Drug Products were shipped thereafter.

Patel Decl, Ex. I.

On January 14, 2010 – more than three months after the last Drug Products were delivered to Vision New Jersey's Memphis, Tennessee warehouse – Sunrise received a warning letter from a district office of the FDA (the “January 14, 2010 Warning Letter”). Complaint, Ex. B. No later than February 2, 2010, Sunrise informed Vision Florida that it had received the January 14, 2010 Warning Letter.⁵

The January 14, 2010 Warning Letter outlines alleged violations by Sunrise of Current Good Manufacturing Practice (“CGMP”) regulations for Finished Pharmaceuticals, labels the Drug Products as “adulterated” and asserts that the Drug Products are “unapproved new drugs.” It bears emphasis that Vision Florida does not – and cannot – allege that it was unaware of the unapproved nature of the Drug Products.⁶

The January 14, 2010 Warning Letter concludes that failure to correct these alleged violations “may result in legal action” (emphasis added). Vision Florida does not – and cannot – allege that the FDA commenced enforcement proceedings.

⁵ A copy of an e mail from Sunrise to Vision Florida dated February 2, 2010 discussing the January 14, 2010 Warning Letter is annexed to the Patel Decl as Exhibit K.

⁶ Vision Florida knows well that many drugs – including the Drug Products – are lawfully marketed without FDA approval. Indeed, in Mutual Pharmaceutical Company, Inc. et al. v. Watson Pharmaceuticals, Inc., et al., Case No. CV 09-05700 PA (RCx), United States District Court, Central District of California, Vision Florida took the position in its motion to dismiss the complaint that Colchicine – one of the Drug Products – is not a new drug and may be marketed without FDA approval. Vision Florida's Memorandum of Law in Support of Motion to Dismiss dated September 23, 2009 (“Motion to Dismiss Mutual Pharmaceutical Complaint”) at 4. A copy of Vision Florida's Motion to Dismiss Mutual Pharmaceutical Complaint is annexed to the Patel Decl as Exhibit J. Vision Florida correctly recognized that “[w]hen new drugs are marketed without prior review, the FDA must decide whether and how to initiate enforcement proceedings. The enforcement provisions of the FDCA ‘authorize, but do not compel’ the FDA to undertake enforcement activity.” Motion to Dismiss Mutual Pharmaceutical Complaint, at 11.

On April 29, 2010 – six and one-half months after the last Drug Products were delivered to Vision New Jersey’s Memphis, Tennessee warehouse – Vision Florida received a warning letter from a district office of the FDA (the “April 29, 2010 Warning Letter”). Complaint, Ex. A. The April 29, 2010 Warning Letter reiterated the district office’s position that the Drug Products were unapproved and “adulterated” and concludes that failure to take corrective action “may result in legal action.” (Emphasis added.) Vision Florida does not – and cannot – allege that the FDA commenced enforcement proceedings.

It is well known in the pharmaceutical industry that warning letters from the FDA are unenforceable and advisory in nature. Indeed, Section 4-1-1 of the FDA Regulatory Procedures Manual states: “A Warning Letter is informal and advisory. It communicates the agency’s position on a matter, but it does not commit the FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued.”⁷

Notwithstanding the foregoing, Vision Florida relies exclusively on the unenforceable advisory warning letters as the basis for its complaint. It bears emphasis that Vision Florida does not allege that the Drug Products in general are defective or that the particular Drug Products delivered to Vision New Jersey were defective upon delivery or at any time thereafter. Rather, Vision Florida alleges merely that the warning letters – issued months after the last Drug Products were delivered to Vision New Jersey -- identify the Drug Products as unapproved and “adulterated” and advise Vision Florida that it may not introduce the Drug Products into interstate commerce.

⁷ A copy of Section 4-1-1 of the FDA Regulatory Procedures Manual is annexed to the Patel Decl as Exhibit L.

Based on the foregoing, Vision Florida asserts seven claims against Sunrise for breach of contract, breach of implied warranty of merchantability, breach of implied warranty of fitness for a particular purpose, breach of covenant of good faith and fair dealing, unjust enrichment, negligence and deceptive trade practice.

The only jurisdictional allegations contained in the Complaint are (a) “[t]his Court has personal jurisdiction over Defendant by virtue of its transaction of business in the State of New York and in this District” and (b) “The ordinary purpose of the Drug Products is for retail distribution into interstate commerce (including to pharmacies within this District for distribution to District residents).” Complaint, ¶¶ 3 and 43. In fact, Sunrise did not transact any business in New York relating to the Drug Products or its relationship with Vision New Jersey or Vision Florida, nor did Sunrise contract to supply the Drug Products in New York. Patel Decl, ¶¶ 3, 8, 9, 14, 15 and 16 and Exhibits E, F, G, H and I. The Drug Products were manufactured in New Jersey on behalf of a New Jersey customer and were shipped to Tennessee. Patel Decl, ¶¶ 3, 8 and 9 and Exhibits H and I.

Moreover, at the time this action was commenced, (a) Sunrise was a corporation formed under the laws of New Jersey; (b) Sunrise’s offices and all other Sunrise facilities were located in New Jersey; (c) Sunrise did not maintain an office in New York; (d) Sunrise did not maintain a manufacturing facility in New York; (e) Sunrise did not maintain a laboratory in New York; (f) Sunrise did not maintain a warehouse in New York; (g) Sunrise did not have a bank account in New York; (h) Sunrise did not have an employee in New York; (i) Sunrise did not have a sales representative or other agent in New York; (j) Sunrise did not have a telephone number or telephone listing in New York;

(k) Sunrise did not have a retail or wholesale customer in New York; (l) Sunrise did not ship products of any nature into New York; (m) Sunrise did not own or lease real property in New York; (n) Sunrise did not do or transact business in New York; (o) Sunrise was not licensed or registered to do or transact business in New York; and (p) Sunrise did not solicit business in New York. Patel Decl, ¶¶ 18 – 23.

Accordingly, there is no basis for this Court to exercise personal jurisdiction over Sunrise.

Point I

The Court Lacks Personal Jurisdiction Over Sunrise

Sunrise is entitled to dismissal under Fed. R. Civ. P. 12(b)(2) because the Court lacks personal jurisdiction over it. As demonstrated in the accompanying Patel Decl and the irrefutable documentary evidence annexed thereto, there is no basis for personal jurisdiction over Sunrise in this Court.

New York provides for jurisdiction over a foreign defendant on two alternative bases: general jurisdiction under CPLR 301 and specific or long arm jurisdiction under CPLR 302. As set forth below, the Court lacks personal jurisdiction over Sunrise under both statutes.

A. The Court Lacks General Personal Jurisdiction Under CPLR 301

CPLR 301 provides for personal jurisdiction over a non-domiciliary who is “doing business” in the State of New York. The non-domiciliary must be “engaged in such a continuous and systematic course of ‘doing business’ [in New York] as to warrant a finding of its ‘presence’” here. McGowan v. Smith, 52 N.Y.2d 268, 272, 437 N.Y.S.2d 643 (1081) (internal quotation omitted). “The court must be able to say from the facts

that the corporation is ‘present’ in the State ‘not occasionally or casually, but with a fair measure of permanence and continuity.’” Landoil Resources Corp. v. Alexander & Alexander Services, Inc., 77 N.Y.2d 28, 33-34, 563 N.Y.S.2d 739, 741 (1990). Thus, general jurisdiction is dependent upon a showing that the corporation is doing business in New York systematically, continuously, and with a fair measure of permanence.

In determining whether general personal jurisdiction exists under CPLR 301, courts generally focus on the existence of an office in New York, solicitation of business in New York, the presence of bank accounts in New York, the presence of property in New York and the presence of employees and agents in New York. Yurman Designs, Inc. v. A. R. Morris Jewelers, L.L.C., 41 F. Supp. 2d 453, 457 - 458 (S.D.N.Y. 1999)

Moreover, for the purpose of general personal jurisdiction under CPLR 301, an entity’s presence in New York is determined as of the time the lawsuit is commenced – not the time the claim arose. Id. at 457; The William Systems, Ltd. v. Total Freight Systems, Inc., 27 F. Supp. 2d 386, 388 (E.D.N.Y. 1998) (“[t]o obtain jurisdiction under CPLR 301, defendant must be doing business at the time the action is brought, not when the cause of action arose”).

Here, Sunrise had no connection whatsoever with the State of New York at the time Vision Florida commenced this action. Indeed, at the time Vision Florida commenced this action: (a) Sunrise was a corporation formed under the laws of New Jersey; (b) Sunrise’s offices and all other Sunrise facilities were located in New Jersey; (c) Sunrise did not maintain an office in New York; (d) Sunrise did not maintain a manufacturing facility in New York; (e) Sunrise did not maintain a laboratory in New York; (f) Sunrise did not maintain a warehouse in New York; (g) Sunrise did not have a

bank account in New York; (h) Sunrise did not have an employee in New York; (i) Sunrise did not have a sales representative or other agent in New York; (j) Sunrise did not have a telephone number or telephone listing in New York; (k) Sunrise did not have a retail or wholesale customer in New York; (l) Sunrise did not ship products of any nature into New York; (m) Sunrise did not own or lease real property in New York; (n) Sunrise did not do or transact business in New York; (o) Sunrise was not licensed or registered to do or transact business in New York; and (p) Sunrise did not solicit business in New York. Patel Decl, ¶¶ 16 - 23.

Vision Florida does not allege – and cannot allege – that Sunrise is doing business or is otherwise present in the State of New York. Accordingly, there is no basis for the Court to exercise general personal jurisdiction over Sunrise pursuant to CPLR 301.

B. The Court Lacks Specific Personal Jurisdiction Under CPLR 302(a)

New York's long arm statute provides no basis for personal jurisdiction over Sunrise, and Vision Florida's attempt to invoke New York's long arm statute is without merit. "A plaintiff bears the burden of demonstrating personal jurisdiction...." Eternal Asia Supply Chain Management (USA) Corp. v. Chen, 2013 U.S. Dist. LEXIS 59538, *7 (S.D.N.Y. April 25, 2013)⁸. Mere conclusory allegations are insufficient to support a prima facie showing of personal jurisdiction and the allegations must be well pled. Id. at *8 Here, the only allegations contained in the complaint regarding personal jurisdiction are:

- "This Court has personal jurisdiction over Defendant by virtue of its transaction of business in the State of New York and in this District." (Complaint, ¶ 3)

⁸ A copy of this decision is attached hereto as Exhibit 1

• “The ordinary purpose of the Drug Products is for retail distribution into interstate commerce (including to pharmacies within this District for distribution to District residents).” (Complaint, ¶ 43)

1. There Is No Personal Jurisdiction Under CPLR 302(a)(1)

CPLR 302(a)(1) extends jurisdiction over a nondomiciliary who “transacts any business” in New York or “contracts anywhere to supply goods or services” in New York provided that the cause of action arises from such transaction of business or provision of goods or services. Jurisdiction under CPLR 302(a)(1) requires a showing that a defendant purposefully availed itself of the privilege of doing business in New York and that the defendant could foresee being brought into court in New York. Aqua Prods., Inc. v. Smartpool, Inc., 2005 U.S. Dist. LEXIS 17246 *16 (S.D.N.Y. August 18, 2005).⁹ With regard to contracts, CPLR 302(a)(1) applies only where an action arises out of the contract itself, such as where a non-domiciliary defendant contracts with a New York company for performance in New York, and then fails to pay for the services. A.I. Trade Finance, Inc. v. Petra Bank, 989 F.2d 76, 80 (2d Cir. 1993); see also Finest Fruits, Inc. v. Bertuca, 714 F. Supp. 94, 97 (S.D.N.Y. 1989) (CPLR 302(a)(1) provides for jurisdiction “where a non-domiciliary enters into a contract to do work or to send goods into New York, so long as the cause of action arises out of the contract”).

A cause of action “arises out of” a defendant’s activities in New York when there exists a “substantial nexus” between the actions occurring in the state and the claim sued upon. Aqua Prods., Inc. v. Smartpool, Inc., 2005 U.S. Dist. LEXIS 17246 *17 (S.D.N.Y. August 18, 2005).

⁹ A copy of this decision is attached hereto as Exhibit 2.

Here, Vision Florida's naked assertion that Sunrise transacts business in New York is without merit. Vision Florida does not – and cannot – identify a single transaction of business in New York on the part of Sunrise which bears any relationship, let alone a “substantial relationship” to its claims. Moreover, Vision Florida does not – and cannot – allege that Sunrise contracted to supply the Drug Products in New York.

Indeed, all of the Drug Products were manufactured in Sunrise's New Jersey facilities on behalf of a New Jersey customer and shipped to a third-party warehouse in Memphis, Tennessee. Patel Decl, ¶¶ 3, 4, 8 and 9 and Exhibits H and I. The Purchase Orders expressly direct Sunrise to ship the Drug Products to Memphis Tennessee. Patel Decl, ¶ 9 and Exhibits H and I thereto. The Manufacturing Agreements were entered into by Sunrise, a New Jersey corporation, and Vision New Jersey, a New Jersey limited liability company. Patel Decl, ¶¶ 3 and 4 and Exhibits A and C. Vision Florida does not even allege that it, Vision New Jersey or Sunrise maintained offices or other facilities in New York. Accordingly, there is no basis for personal jurisdiction under CPLR 302(a)(1).

2. There Is No Personal Jurisdiction Under CPLR 302(a)(2)

Subsection (a)(2) of CPLR 302 extends jurisdiction over a nondomiciliary who “commits a tortious act within the state” provided that the cause of action arises from such tortious act. It is well settled that this prong requires the defendant to have committed a tort while physically present in New York. Bensusan Rest. Corp. v. King, 126 F.3d 25, 29 (2d Cir. 1997); Aqua Prods., 2005 U.S. Dist. LEXIS 17246 (holding sale of allegedly infringing products occurs where sales are made, not where products are shipped); Overseas Media, Inc. v. Skvortsov, 407 F. Supp. 2d 563, 572 (S.D.N.Y. 2005)

(holding offers to sell allegedly infringing program content were not torts in New York where offerors were located in Russia).

Here, Vision Florida does not allege – and cannot allege – that Sunrise engaged in tortious conduct while present in New York. Indeed, all of the Drug Products were manufactured in New Jersey and shipped to Tennessee.

3. There Is No Personal Jurisdiction Under CPLR 302(a)(3)

In order to establish personal jurisdiction under CPLR 302(a)(3), Sunrise must have committed a tortious act outside New York causing injury to person or property in New York, but only if Sunrise (i) regularly does or solicits business, or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered, in New York, or (ii) expects or should reasonably have expected the act to have consequences in New York and derives substantial revenue from interstate or international commerce.

Here, Vision Florida does not – and cannot – allege that it was injured in New York by reason of a tort committed by Sunrise outside of New York. Indeed, neither Vision Florida nor Vision New Jersey is located in New York. Vision Florida does not – and cannot -- allege that Sunrise regularly does or solicits business or engages in any other persistent course of conduct, or derives substantial revenue from goods used or consumed or services rendered in New York. Sunrise does not now, and did not at the time Vision Florida commenced this action or at any time thereafter do business in New York, transact business in New York, solicit business in New York, engage in any activity in New York, have customers, employees or agents in New York, or derive any

revenue from goods used or consumed or services rendered in New York. Patel Decl, ¶¶ 19 – 23.

Moreover, Vision Florida does not allege -- and cannot allege -- that Sunrise expected or reasonably should have expected its manufacture of the Drug Products to have consequences in New York. The Drug Products were delivered to Tennessee -- not New York. Patel Decl, ¶ 9 and Exhibit H and I thereto. Vision Florida does not allege -- and cannot allege -- that Sunrise derives substantial revenue from interstate or international commerce. In fact, Sunrise does not now, and did not at the time Vision Florida commenced this action or at any time thereafter derive substantial revenue from interstate or international commerce. Patel Decl, ¶ 21.

4. There Is No Personal Jurisdiction Under CPLR 302(a)(4)

The Court does not have personal jurisdiction over Sunrise under CPLR 302(a)(4) because Sunrise does not own, use or possess any real property situated within New York. Patel Decl, ¶ 20.

Accordingly, this action must be dismissed because the Court lacks personal jurisdiction over Sunrise

Point II

The Vision Florida Lacks Standing

Vision Florida lacks standing to assert the claims contained in the complaint because Vision Florida has no connection whatsoever to the contracts, transactions or events identified in the complaint and which form the bases of Vision Florida's claims. Vision Florida is not a party to the Manufacturing Agreements -- indeed, Vision Florida was not even created until August 28, 2009 -- long after Vision New Jersey engaged

Sunrise to manufacture the Drug Products. See Patel Decl, Exhibit A. None of the accepted Purchase Orders originated from Vision Florida, and none of the Drug Products were delivered to Vision Florida. See Purchase Orders and Packing Slips.

All of Sunrise's dealings with respect to the Drug Products were with Vision New Jersey. The Manufacturing Agreements are between Sunrise and Vision New Jersey (see Manufacturing Agreements, Patel Decl, Exhibits E, F and G); the Purchase Orders were issued by Vision New Jersey (see Purchase Orders, Patel Decl, Exhibit H); and the Drug Products were shipped to Vision New Jersey's warehouse in Memphis Tennessee (see Packing Slips, Patel Decl, Exhibit I). It bears emphasis that Vision Florida fails to allege any relationship between Vision Florida and Vision New Jersey.

"A plaintiff must demonstrate standing for each claim and form of relief sought."¹⁰ Baur v. Veneman, 352 F.3d 625, 642 n.15 (2d Cir. 2003). The standing doctrine requires Vision Florida to show: (1) an injury-in-fact and an invasion of a legally protected interest which is (a) concrete and particularized, and (b) actual or imminent and not conjectural or hypothetical; (2) a causal connection between the injury and the conduct complained of; and (3) that the injury is likely to be redressed by the requested relief. Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc., 528 U.S. 167, 180-181 (2000) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-561 (1992)). Injury-in-fact means that injury must be "certainly impending." Lujan, 504 U.S. at 563 n.2. The casual connection element "requires that a federal court act only to redress injury

¹⁰ "A case is properly dismissed for lack of subject matter jurisdiction under Rule 12(b)(1) when the district court lacks the statutory or constitutional power to adjudicate it." Lockett v. Bure, 290 F.3d 493, 496 (2d Cir. 2002). "[T]he plaintiff asserting subject matter jurisdiction has the burden of proving by a preponderance of the evidence that it exists." *Id.* at 497. While inferences are to be drawn in the plaintiff's favor, "no presumptive truthfulness attaches to the complaint's jurisdictional allegations." Sloan v. Truong, 573 F. Supp. 2d 823 (S.D.N.Y. 2008).

that fairly can be traced to the challenged action of the defendant, and not injury that results from independent action of some third-party not before the court. Simon v. Eastern Ky. Welfare Rights Org., 426 U.S. 26, 41-42 (1976). To avoid a hypothetical or abstract dispute, a court examines “whether the facts alleged, under all of the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to justify judicial resolution.” Port Washington Teacher’s Ass’n v. Board of Educ. Of the Port Washington Union Free Sch. Dist., 478 F.3d 494, 501 (2d Cir. 2007) (quoting Marchi v. Bd. Of Coop. Educ. Servs. Of Albany, 173 F.3d 469, 478 (2d Cir. 1999)).

Here, Vision Florida cannot demonstrate standing because it has no relationship whatsoever to the claims contained in the complaint. Accordingly, the complaint must be dismissed with prejudice.

Point III

Vision New Jersey Is A Required Party

This action must be dismissed because Vision New Jersey is a necessary and indispensable party which should – but cannot – be joined as a party because its joinder would defeat diversity jurisdiction. To dismiss an action pursuant to Fed. R. Civ. P. 12(b)(7) for failure to join a “required” party pursuant to Fed. R. Civ. P. 19, a court must undertake a two-step inquiry. See Global Discount Travel Services, LLC v. Trans World Airlines, 960 F. Supp. 701, 707 (S.D.N.Y. 1997).¹¹ First the Court must determine if an absent party’s presence is “necessary” under Fed. R. Civ. P. 19(a). See

¹¹ The Federal Rules of Civil Procedure no longer include the terms “necessary” or “indispensable.” See Fed. R. Civ. P. Advisory Committee’s notes to 2007 amendment. Sunrise uses those terms in its memorandum of law solely for purposes of convenience and clarity. There is no “substantive difference between the present rule [19] and the rule as applied by the district court prior to the 2007 amendment.” CP Solutions PTE, Ltd. v. Gen. Elec. Co., 552 F.3d 156, 159 n. 2 (2d Cir. 2009).

Alex Charts and Charting Assoc., Inc. v. Nationwide Mut. Ins. Co., 16 Fed. Appx 44, 46 (2d Cir. 2001). A party is “necessary” under Rule 19(a) where one of the following criteria is met: (1) “in that person’s absence, the court cannot accord complete relief among existing parties;” (2) the absent party “claims an interest relating to the subject of the action” and will be prejudiced by non-joinder; or (3) the absence of a party will “leave an existing party subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations because of the interest.” Fed. R. Civ. P. 19(a).

Second, if the absent party is necessary, but joinder is not feasible because it would destroy diversity jurisdiction, the court must then determine whether the party is “indispensable” within the meaning of Fed. R. Civ. P. 19(b), i.e., whether “‘in equity and good conscience,’ that the case should not proceed without the party.” Pik v. Institute of Int’l Educ., 2008 U.S. Dist. LEXIS 95676 *10 (S.D.N.Y. November 10, 2008)¹² (citing Fed. R. Civ. P. 19(b)). In making this determination, the court considers four factors:

“[F]irst, to what extent a judgment rendered in the person’s absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person’s absence would be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.”

ConnTech Dev. Co. v. Univ. of Conn. Educ. Prop., Inc., 102 F.3d 677, 682 (2d Cir. 1996) (citing Fed. R. Civ. P. 19(b)). If, after weighing the four factors, the court determines that the party is indispensable, and its joinder will defeat jurisdiction, the court must dismiss the action. Environtech Corp. v. Bethlehem Steel Corp., 729 F.2d 70, 77-78 (2d Cir. 1984) (holding that plaintiff was an indispensable party to defendant’s

¹² A copy of this decision is attached hereto as Exhibit 3.

counterclaim and upholding the dismissal of the counterclaim for lack of subject matter jurisdiction); German v. Federal Home Loan Mortg. Corp., 885 F. Supp. 537, 579 (S.D.N.Y. 1995) (“If the Court determines that the case may not proceed in the party’s absence, the party is considered ‘indispensable,’ and the action should be dismissed.”).

Vision New Jersey Is A Necessary Party

It is well-established that a party to the contract at issue in a lawsuit is necessary because “complete relief cannot be accorded in that party’s absence.” Ryan v. Volpone Stamp Co., 107 F. Supp. 2d 369, 387 (S.D.N.Y. 2000); see also Global Detection and Reporting, Inc. v. Securetec Detektions-Systeme AG, 2008 U.S. Dist. LEXIS 95038 *3-4 (S.D.N.Y. November 21, 2008)¹³ (same); Global Discount, 960 F. Supp. at 707-08 (“As a direct party to the contract which is under dispute, Karabu is a necessary party to this litigation for at least three reasons articulated under Federal Rule of Civil Procedure Rule 19(a).”). Courts have repeatedly characterized parties to the underlying contract as necessary because: (1) a contract involves that party’s rights, as well as the other litigant’s rights; (2) the absent party’s interests could be impaired or impeded by a determination of its duties or obligations under the contract; and (3) the absence of that party could place the remaining parties at risk of multiple or inconsistent obligations in subsequent or parallel proceedings. See Global Discount, 960 F. Supp. at 707-08.

Here, Vision New Jersey is an essential party to the Manufacturing Agreements which are the focus of Vision Florida’s claims. Accordingly, Vision New Jersey is a necessary party.

¹³ A copy of this decision is attached hereto as Exhibit 4.

Vision New Jersey Is An Indispensable Party

Under the four factors contained in Rule 19(b), Vision New Jersey is an indispensable party. Vision Florida seeks damages for Sunrise's alleged breach of the Manufacturing Agreements. Vision New Jersey is a party to the Manufacturing Agreements. Any determination regarding the rights and obligations of the parties to the Manufacturing Agreements will directly affect Vision New Jersey and may very well prejudice Vision New Jersey's ability to enforce the Manufacturing Agreement. Moreover, Sunrise may be subjected to multiple, inconsistent or duplicative claims and orders with respect to the Manufacturing Agreements if Vision New Jersey is not a party to this action.

There is no protective measure that could prevent this prejudice to the parties. Moreover, no judgment rendered in Vision New Jersey's absence can be adequate. An action without Vision New Jersey will leave Sunrise susceptible to duplicative litigation by Vision New Jersey in a different forum resulting in the waste of party resources and judicial resources. It bears emphasis that Vision Florida has an adequate alternative remedy if this action is dismissed: Vision Florida can re-commence this action against Sunrise in New Jersey State Court.

Accordingly, Vision New Jersey is a necessary and indispensable party. Because the joinder of Vision New Jersey will defeat diversity jurisdiction, this action must be dismissed.

Point IV

The Complaint Fails To State A Claim Upon Which Relief May Be Granted

In order to avoid dismissal under Fed. R. Civ. P. 12(b)(6), a plaintiff must allege “enough facts to state a claim of relief that is plausible on its face.” Rosenson v. Mordowitz, 2012 U.S. Dist. LEXIS 120077, at *8 (S.D.N.Y. Aug. 23, 2012).¹⁴ A claim is facially plausible “when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id. While the court must accept as true all well-pleaded factual allegations and draw all inferences in the plaintiff’s favor, a court does not accept as true legal conclusions couched as factual allegations. Id. at *9. Thus, neither “a formulaic recitation of the elements of a cause of action” nor “naked assertion[s] devoid of further factual enhancement” suffice to state a claim. Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009); see also Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007). “[W]here well-pleaded facts do not permit the court to infer more than a mere possibility of misconduct, the complaint has alleged – but has not shown – that the pleader is entitled to relief.” Iqbal, 556 U.S. at 679.

A. Vision Florida Fails To Allege That The Drug Products Are Adulterated

Vision Florida fails to allege sufficient facts from which the Court may infer that its claims for relief are plausible and that Sunrise is liable. Indeed, Sunrise Florida fails to allege that the specific Drug Products delivered to Vision New Jersey were adulterated upon tender of delivery or at any time thereafter. Vision Florida does not even allege that the Drug Products in general are adulterated. Rather, Vision Florida alleges only

¹⁴ A copy of this decision is attached hereto as Exhibit 5.

that the FDA issued warning letters which labeled unidentified batches of the Drug Products as adulterated. As a matter of law, a warning letter from the FDA is merely advisory, does not constitute the final binding position of the FDA and does not bind the FDA to take enforcement action. Indeed, Section 4-1-1 of the FDA Regulatory Procedures Manual states: "A Warning Letter is informal and advisory. It communicates the agency's position on a matter, but it does not commit the FDA to taking enforcement action. For these reasons, FDA does not consider Warning Letters to be final agency action on which it can be sued." A copy of Section 4-1-1 of the FDA Regulatory Procedures Manual is annexed to the Patel Decl as Exhibit L.

Moreover, the January 14, 2010 Warning Letter and the April 29, 2010 Warning Letter were issued many months after the last Drug Products were delivered to Vision New Jersey. The last two Purchase Orders for the Drug Products were issued by Vision New Jersey on August 3, 2009 for Hyoscyamine Sulfate for a total purchase price of \$68,756.60 and on September 11, 2009 for Colchicine for a total purchase price of \$36,000. See Purchase Orders, Patel Decl, Ex. H. The Hyoscyamine Sulfate was shipped to Vision New Jersey's Memphis, Tennessee warehouse on August 19, 2009 and the Colchicine was shipped to Vision New Jersey's Memphis, Tennessee warehouse on October 9, 2009. See Packing Slips, Patel Decl, Ex. I. No Drug Products were shipped thereafter. See Packing Slips, Patel Decl, Ex. I.

Vision Florida fails to allege a causal nexus between the advisory warning letters which were issued months after the Drug Products were delivered to Vision New Jersey and its alleged damages. Indeed, Vision Florida does not allege that the FDA ordered a recall of any particular batch of the Drug Products or that Vision Florida was prevented

from re-selling any particular batch of the Drug Products. Vision Florida's failure to identify the dates of the transactions and the specific batches of the Drug Products which form the bases of its claims further demonstrates that it has failed to plead sufficient facts to state a claim of relief that is plausible on its face.

Accordingly, Vision Florida fails to state a claim upon which relief may be granted.

B. Vision Florida's Contract And Warranty Claims
Relating To Transactions Which Occurred Prior To
April 10, 2009 Are Barred By The Statute Of Limitations

Regardless of whether New York or New Jersey law is applied, the statute of limitations for warranties and contracts relating to the sale of goods is four years.

N.Y.U.C.C. § 2-725 (statute of limitations for claims of breach of contract and breach of warranty is four years from the date of delivery); N.J. Stat. Ann. § 12A:2-725 (2011) ("An action for breach of any contract for sale must be commenced within four years after the cause of action has accrued"). This action was commenced on April 10, 2013 and relates to contracts and transactions dating back to 2006. Complaint, ¶ 8. Because Vision Florida fails to identify the dates of the specific transactions which form the bases of its claims, it is not possible to identify the extent to which Vision Florida's claims are barred by the statute of limitations. However, all of Vision Florida's claims sounding in contract and warranty are barred by the statute of limitations to the extent they are based on transactions prior to April 10, 2009.

C. The Alleged Oral Agreement Regarding
The Sale Of The Drug Products Is Barred
By The Statute Of Frauds

Vision Florida's allegation that the Manufacturing Agreements obligated Sunrise to inform it about 483 observations, FDA warning letters and related correspondence (See Complaint, ¶ 10) is without merit. The Manufacturing Agreements contain no such provisions. See Manufacturing Agreements. Similarly without merit is Vision Florida's allegation that it "also had a verbal agreement that Sunrise would advise Vision of any 483 observations or FDA warning letters." Sunrise fails to plead basic facts about the alleged oral agreement such as the date of the agreement and the identity of the individuals who made the agreement. Moreover, under New York and New Jersey law, "a contract for the sale of goods for the price of \$500 or more is not enforceable by way of action or defense unless there is some writing sufficient to indicate that a contract for sale has been made between the parties and signed by the party against whom enforcement is sought or by his authorized agent or broker." N.Y.U.C.C. § 2-201; N.J. Stat. Ann. § 12A:2-201. Here, Vision Florida's alleged oral agreement regarding the sale of the Drug Products is barred by the statute of frauds. In all events, documentary evidence conclusively demonstrates that Sunrise informed Vision Florida about the January 14, 2010 Warning Letter no later than February 2, 2010. See Patel Decl, Ex. K.

D. Vision Florida's Claim For Negligence
Is Duplicative Of Its Claim For
Breach Of Contract

Under New Jersey law, a "dispute that clearly arises out of and relates to a contract and its breach sounds in contract and not in tort." Die Casters International v.

United States of America, 2009 U.S. Dist. LEXIS 90541 (D.N.J. September 29, 2009)¹⁵; Stewart Title Guaranty Co. v. Greenlands Realty, L.L.C., 58 F. Supp. 2d 370, 386 (D.N.J. 1999) (same).¹⁶ Here, Vision Florida alleges that Sunrise breached the Manufacturing Agreements by failing to notify Vision Florida about its correspondence with the FDA and selling Drug Products which were deemed adulterated in the FDA warning letters. Complaint, ¶¶ 29 – 40. Vision Florida's negligence claim is identical – Vision Florida alleges that Sunrise had a duty to manufacture the Drug Products in compliance with FDA regulations and notify Vision Florida about violations of FDA regulations. Complaint, ¶¶ 77 – 81. Moreover, the January 14, 2010 Warning Letter and April 29, 2010 Warning Letter are advisory and unenforceable and thus cannot form the basis of a breach of an independent duty of care. Patel Decl, Ex. L. Accordingly, Vision Florida's negligence claim must be dismissed.

E. Vision Florida's Claim For Breach Of Covenant Of Good Faith And Fair Dealing Is Duplicative Of Its Claim For Breach Of Contract

Under New Jersey law, in order to state a claim for breach of the implied covenant of good faith and fair dealing, Vision Florida must allege facts which demonstrate, among other things, that Sunrise “engaged in conduct, apart from its contractual obligations, without good faith and for the purpose of depriving the plaintiff of the rights and benefits under the contract.” Jartas v. Bank of America Corp., 2010 U.S. Dist. LEXIS 135815 *24 (D.N.J. December 23, 2010)¹⁷ (emphasis added). Here, Vision

¹⁵ A copy of this decision is attached hereto as Exhibit 6.

¹⁶ Under New York law, Vision Florida's attempt to convert its contract claim into a tort claim is similarly without merit. Clark-Fitzpatrick, Inc. v. Long Island Rail Road Company, 70 N.Y.2d 382, 521 N.Y.S.2d 653, 656 (1987) (“[i]t is a well established principle that a simple breach of contract is not to be considered a tort unless a legal duty independent of the contract itself has been violated. This legal duty must spring from circumstances extraneous to, and not constituting elements of, the contract...”)

¹⁷ A copy of this decision is attached hereto as Exhibit 7.

Florida's claim for breach of contract and breach of the implied covenant of good faith and fair dealing are based on the same allegation: That Sunrise provided Drug Products which were allegedly "unsaleable" (Breach of Contract, Complaint, ¶ 37) and "not salable" (Breach of Implied Covenant of Good Faith and Fair Dealing, Complaint, ¶ 66). Accordingly, Vision Florida does not – and cannot – state a claim for breach of the implied covenant of good faith and fair dealing.¹⁸

F. Vision Florida Fails To Allege That
The Drug Products Were Defective
Upon Tender Of Delivery

Under New Jersey and New York law, a warranty is breached, if at all, upon tender of delivery. N.J. Stat. Ann. § 12A:2-725(2) ("a breach of warranty occurs when tender of delivery is made..."); N.Y.U.C.C. § 2-725(2) ("a breach of warranty occurs when tender of delivery is made..."). Here, Vision Florida does not – and cannot – allege that the Drug Products were defective upon tender of delivery. Indeed, the January 14, 2010 Warning Letter and April 29, 2010 Warning Letter – which are the only basis for Vision Florida's allegation that the Drug Products are adulterated – were issued months after the last of the Drug Products were delivered to Vision New Jersey. See Packing Slips, Patel Decl, Ex. I.

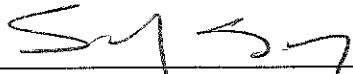
Conclusion

For all of the foregoing reasons, the complaint should be dismissed with prejudice.

¹⁸ Under New York law, Vision Florida's claim for breach of the covenant of good faith and fair dealing is similarly without merit. Mars Advertising Europe Limited v. Young & Rubicam, Inc., 2013 U.S. Dist. LEXIS 60389 *23 (S.D.N.Y. April 24, 2013) (a claim for breach of implied covenant of good faith and fair dealing "may be brought, if at all, only if it is based on allegations different than those underlying the accompanying breach of contract claim"). A copy of this decision is attached hereto as Exhibit 8.

Dated: New York, New York
June 25, 2013

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